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No. 98-198

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IN THE
Supreme Court of the United States
OCTOBER TERM, 1998

JOSEPH F. WHELAN, *et al.*,
Petitioners,

v.

MERRELL DOW PHARMACEUTICALS INC.,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

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BRIEF IN OPPOSITION

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QUESTION PRESENTED

Whether this Court should review the decision of the District of Columbia Circuit summarily affirming the dismissal of petitioners' claims that Bendectin caused Joseph F. Whelan's birth defects, when that decision is consistent with this Court's decision in *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and the final decisions of every federal appellate court that has considered a Bendectin case, which have held either that plaintiffs' Bendectin evidence is inadmissible or insufficient to prove that Bendectin causes birth defects?

RULE 29.6 STATEMENT

As to parent corporations, respondent Merrell Pharmaceuticals Inc. (which is sued in this case under its former name, Merrell Dow Pharmaceuticals Inc.) is a wholly-owned subsidiary of Hoechst Marion Roussel Inc. The two stockholders of Hoechst Marion Roussel, Inc. are HMR Pharma, Inc. and Hoechst Marion Roussel, S.A. HMR Pharma, Inc. is wholly owned by Hoechst Marion Roussel AG, which in turn is a wholly-owned subsidiary of Hoechst AG. Hoechst AG wholly owns Hoechst Celanese Corporation and Hoechst Corporation. Hoechst Corporation wholly owns HCCP Acquisition Corporation, which owns 52.94% of Copley Pharmaceuticals Inc.

Merrell Pharmaceuticals Inc. has three nonwholly-owned foreign subsidiaries in which stock could be publicly available: Marion Merrell S.A. (Spain), Gruppo Lepetit S.p.A. (Italy), and Marion Merrell S.A. (France).

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BRIEF IN OPPOSITION

Respondent Merrell Dow Pharmaceuticals Inc. ("Merrell") respectfully requests that this Court deny the Petition for a Writ of Certiorari seeking review of the decision of the United States Court of Appeals for the District of Columbia Circuit in this case.

COUNTERSTATEMENT

1. In this case, which was filed in 1983, petitioners claim that Joseph F. Whelan's birth defects were caused by his mother's ingestion during pregnancy of Bendectin. Bendectin is a prescription drug manufactured by Merrell for the treatment of morning sickness during pregnancy.

2. In May 1987, the district court granted petitioners' motion to stay this case pending a decision by the D.C. Circuit in another Bendectin case, *Richardson* v. *Richardson-Merrell, Inc.*, 857 F.2d 823 (D.C. Cir. 1988),

cert. denied, 493 U.S. 882 (1989). In September 1988, the D.C. Circuit issued its decision in *Richardson*, finding that with respect to "the oft-asserted claim of causal relationship between Bendectin and birth defects, the drug has been extensively studied and a wealth of published epidemiological data has been amassed, none of which has concluded that the drug is teratogenic."[1] *Richardson*, 857 F.2d at 832.

3. After the *Richardson* decision, the district court in this case issued a Show Cause Order requiring petitioners to "identify specific, admissible expert evidence that they would adduce at trial and that would satisfy their burden on the causation issue in this case, under the requirements of *Richardson* * * *." Pet. App. 12a-13a.

4. The only evidence that petitioners identified in response to the Show Cause Order consisted of four epidemiological studies. The four studies, which were published between 1979 and 1984, were not new. In fact, they were part of the record considered by the D.C. Circuit in *Richardson* and, accordingly, are part of the "overwhelming body" of epidemiological evidence that formed the basis of the *Richardson* decision. *Richardson*, 857 F.2d at 830.

5. In another Bendectin case decided in March 1990, the D.C. Circuit reaffirmed "the binding rule [of law] articulated in *Richardson*," that is, that in absence of some new methodology or evidence different from that considered and rejected in *Richardson*, "an expert opinion that Bendectin is a human teratogen which caused the plaintiff's birth defects is without scientific foundation under Federal Rule of Evidence 703 in the face of 'a wealth of published epidemiological data' to the contrary." *Ealy* v. *Richardson-Merrell, Inc.*, 897 F.2d 1159, 1160 (D.C. Cir.) (quoting *Richardson*, 857 F.2d at 832), *cert. denied*, 498 U.S. 950 (1990).

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[1] A "teratogen" is an agent or factor that causes the production of physical defects in a developing embryo. *Dorland's Illustrated Medical Dictionary* 1669 (28th ed. 1994).

6. In its August 30, 1990 Memorandum Order, the district court dismissed petitioners' claims with prejudice. Pet. App. 11a. In reaching its decision, the district court explained that in responding to the Show Cause Order it was "incumbent upon plaintiffs to demonstrate pursuant to *Richardson* and *Ealy* admissible scientific evidence upon which a jury could reasonably conclude that Bendectin causes [sic] Joseph's birth defects." *Id.* However, because the only evidence that petitioners had identified was four old studies that were part of the *Richardson* record, the district court found that petitioners had "not made the requisite showing" and, therefore, could not proceed to trial. *Id.*

7. In its decision, the district court also rejected petitioners' argument that the holdings of *Richardson* and *Ealy* are limited to Bendectin cases involving limb defects. Specifically, the district court explained that in *Richardson* the D.C. Circuit "carefully took pains to note that it had reviewed the record, including the wealth of published reports on Bendectin, and that *no credible and admissible scientific evidence exists that would establish the drug as a human teratogen.*" *Id.* 9a (emphasis supplied). Thus, "there is nothing implicit or explicit that restricts the holding of *Richardson* and *Ealy* solely to limb defects" because "[b]oth cases discuss more broadly the question of whether Bendectin is a human teratogen." *Id.* 9a-10a.

8. Petitioners filed a motion to vacate the district court's August 30 Memorandum Opinion, but in their motion they failed to present any new evidence or legal arguments. Instead, the only evidence that petitioners identified was the same four old epidemiological studies that the district court had rejected in its Memorandum Opinion. *See id.* 11a.

9. Before the district court decided petitioners' motion to vacate, the D.C. Circuit issued yet another Bendectin decision that reaffirmed the *Richardson* and *Ealy* holdings. *Raynor* v. *Merrell Pharmaceuticals Inc.*, 104 F.3d 1371, 1374 (D.C. Cir. 1997) ("[i]f we were to consider this

case under Rule 703, nothing would compel us to deviate from our holding in *Richardson*"). In the *Raynor* decision, the D.C. Circuit also held that the plaintiffs' expert evidence in that case was likewise inadmissible under Federal Rule of Evidence 702, under the factors announced in *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). *See Raynor*, 104 F.3d at 1374-1375.

10. In addition to its admissibility rulings, the *Raynor* court determined that "even if the [plaintiffs'] expert testimony were admissible under *Daubert*, it is unlikely that a jury could reasonably find it sufficient to show causation." 104 F.3d at 1376. In support of that determination, the court highlighted a recent Bendectin decision in which a District of Columbia Superior Court judge "provided an 82-page survey of Bendectin research, and concluded that Merrell had 'established, by clear and convincing evidence, that post-1983 evidence makes it clear that Bendectin *is not a human teratogen* and that "*all responsible scientific thought*" *agrees with this conclusion.*'" *Id.* (quoting *Oxendine* v. *Merrell Dow Pharmaceuticals Inc.*, No. 82-1245, 1996 WL 680992, at *33 (D.C. Super. Ct. Oct. 24, 1996)) (emphasis supplied).

11. In its September 9, 1997 Memorandum Order, the district court denied petitioners' motion to vacate the dismissal of their claims. Pet. App. 4a. Citing the *Raynor* decision, the district court concluded that petitioners had failed to show any "intervening change in controlling law, previously unavailable evidence, or a need to correct a clear legal error or manifest injustice." *Id.*

12. Petitioners appealed the district court's rulings to the D.C. Circuit. In its Order granting Merrell's motion for summary affirmance, the D.C. Circuit explained that "[t]he merits of the parties' positions are so clear as to warrant summary action," and that "[e]ven if the evidence produced by [petitioners] in support of their claim were admissible, no reasonable jury could have found it suffi-

cient to establish causation." *Id.* 2a (citing *Raynor*, 104 F.3d at 1376-1377).

13. Petitioners' petition for rehearing and suggestion for rehearing *en banc* were both denied without recorded dissent. *Id.* 14a, 15a.

REASONS FOR DENYING THE WRIT

I. THE FACT-SPECIFIC BENDECTIN DECISION BELOW WAS CORRECTLY DECIDED, CONSISTENT WITH THIS COURT'S DECISION IN *DAUBERT* v. *MERRELL DOW PHARMACEUTICALS, INC.*

In this case, petitioners were directed by the district court back in 1988 to identify specific, admissible expert evidence other than that which had been rejected by the controlling precedent of *Richardson* that they would adduce at trial to satisfy their burden to show that Bendectin caused Joseph F. Whelan's birth defects. In the ten years since then, the *only* evidence that petitioners have ever identified consisted of four old published epidemiological studies that were part of the record in *Richardson* and, hence, part of the "wealth of published epidemiological data [that] has been amassed, none of which has concluded that the drug is teratogenic." *Richardson*, 857 F.2d at 832.

Because petitioners only identified four studies that were part of the evidence that had already been rejected by the court in *Richardson*, the district court properly determined that they had failed to identify any admissible scientific evidence upon which a jury could reasonably conclude that Bendectin was the cause of Joseph Whelan's birth defects. *See* Pet. App. 11a.

The district court likewise correctly denied petitioners' motion to vacate the dismissal of their claims. *See id.* 4a. By the time of the district court's denial of that motion, the D.C. Circuit had not only confirmed the controlling

precedent of *Richardson* and *Ealy*, but had also determined that a Bendectin plaintiffs' expert evidence failed to satisfy the admissibility requirements of *Daubert*. *See Raynor*, 104 F.3d at 1374-1375. Moreover, based on the current body of scientific evidence concerning Bendectin, the D.C. Circuit had already indicated that regardless of whether the plaintiffs' expert evidence were admissible, "it is unlikely that a jury could reasonably find it sufficient to show" that Bendectin causes birth defects. *See id.* at 1376. Accordingly, the district court in this case properly declined to reconsider the dismissal of petitioners' claims since there was no change in "controlling law, previously unavailable evidence, or a need to correct a clear legal error or manifest injustice." Pet. App. 4a (citing *Raynor*, 104 F.3d at 1376).

Under these circumstances, the D.C. Circuit's decision summarily affirming the dismissal of petitioners' claims was also correct. As that court specifically explained, the "merits of the parties' positions" in this Bendectin case "are * * * clear." *Id.* 2a. Even if the four epidemiological studies that petitioners identified in response to the Show Cause Order were admissible, "no reasonable jury could have found" that those four studies alone were "sufficient to establish" that Bendectin in fact caused Joseph Whelan's particular birth defects. *Id.* (citing *Raynor*, 104 F.3d at 1376-1377).

The summary affirmance by the D.C. Circuit in this case is entirely consistent with the *Daubert* decision. In *Daubert*, this Court set forth standards under Fed. R. Evid. 702 concerning the admissibility of certain expert evidence. *See* 509 U.S. 589-596. In doing so, however, the Court emphasized that "in the event that the trial court concludes that the scintilla of evidence presented [by one party] supporting a position is insufficient to allow a reasonable juror to conclude that the position more likely than not is true," the court should enter judgment as a matter of law in favor of the other party. *Id.* at 596. As examples of such cases, the Court cited

two Bendectin cases from the Fifth and Sixth Circuits, in which the courts had held that the plaintiffs' evidence was insufficient as a matter of law. *Id.* (citing *Turpin* v. *Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349 (6th Cir.), *cert. denied*, 506 U.S. 826 (1992); *Brock* v. *Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307, *modified*, 884 F.2d 166 (5th Cir. 1989), *cert. denied*, 494 U.S. 1046 (1990)).

II. THERE IS NO CONFLICT AMONG THE CIRCUITS

In addition to being consistent with *Daubert*, the decision below is also consistent with the holdings of the final decisions of every other federal appellate court which has considered a Bendectin case.

The federal appellate courts that have considered such issues in Bendectin cases have held either that the plaintiffs' evidence is inadmissible or that it is insufficient as a matter of law to prove causation. Thus, in addition to the D.C. Circuit in *Richardson* and *Ealy*, the Third and Ninth Circuits have found plaintiffs' Bendectin evidence to be inadmissible. *See, e.g., DeLuca* v. *Merrell Dow Pharmaceuticals, Inc.*, 791 F. Supp. 1042 (D.N.J. 1992), *aff'd without op.*, 6 F.3d 778 (3d Cir. 1993), *cert. denied*, 510 U.S. 1044 (1994); *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311 (9th Cir.), *cert. denied*, 516 U.S. 869 (1995). And, in addition to the D.C. Circuit in *Raynor*, the First, Fifth, Sixth, and Tenth Circuits have affirmed that plaintiffs' Bendectin evidence is not sufficient to prove causation. *See, e.g., Elkins* v. *Richardson-Merrell, Inc.*, 8 F.3d 1068 (6th Cir. 1993), *cert. denied*, 510 U.S. 1193 (1994); *Wilson* v. *Merrell Dow Pharmaceuticals Inc.*, 893 F.2d 1149, 1154-1155 (10th Cir. 1990); *Brock* v. *Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307, *modified*, 884 F.2d 166 (5th Cir. 1989), *cert. denied*, 494 U.S. 1046 (1990); *Turpin* v. *Merrell Dow Pharmaceuticals Inc.*, 736 F. Supp. 737 (E.D. Ky. 1990), *aff'd*, 959 F.2d 1349 (6th Cir.), *cert. denied*, 506 U.S. 826 (1992); *Lee* v. *Richardson-Merrell, Inc.*,

772 F. Supp. 1027 (W.D. Tenn. 1991), *aff'd without op.*, 961 F.2d 1577 (6th Cir.), *cert. denied*, 506 U.S. 868 (1992); *Lynch* v. *Merrell-National Laboratories*, 646 F. Supp. 856 (D. Mass. 1986), *aff'd*, 830 F.2d 1190 (1st Cir. 1987).

CONCLUSION

For the foregoing reasons, the petition should be denied.

Respectfully submitted,

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